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5.0 510(K) SUMMARY

OCT 12 2007

Submitter's Name	Gambro Renal Products
Address	10810 West Collins Avenue Lakewood, CO 80215
Establishment Number	2087532
Date of Submission	February 9, 2007
Contact Person	Thomas B. Dowell, Regulatory Affairs Project Manager
Telephone Number **Fax Number**	(303) 231-4094 (303) 542-5138
Name of the Device	Gambro Cartridge® Blood Set
Catalogue Numbers	003409-400 Single Needle 003409-410 Single Needle (with prime line attached) 003410-500 Double Needle 003410-510 Double Needle (with prime line attached) 003410-710 Double Needle (with prime line attached with injection site) 003411-500 Double Needle (with longer patient line) 003412-500 Double Needle - Low Weight 003414-500 Double Needle (with extended dialyzer line) 003414-510 Double Needle (with extended dialyzer line and prime line attached) 003415-510 Double Needle (with prime line attached) 003429-500 Single Needle Conversion Kit
Common or Usual Name	Extracorporeal blood circuit for hemodialysers
Classification Name	Classification Name: Hemodialysis system and accessories Device Class: II Product Code: KOC Regulation Number: 21 CFR 876.5820
Identification of the Legally Marketed Device (Predicate Device)	Cobe Cartridge Blood Tubing Set

Gambro Renal Products
10810 West Collins Avenue
Lakewood, CO 80215

510(k) SUMMARY, continued

Device Description

The Gambro Cartridge® Blood Sets are single use sterile tubing sets employed in the Gambro hemodialysis equipments extracorporeal circulation. They convey the patient's blood from the arterial-venous access fistula to the dialyzing filter (arterial line) and back after purification (venous line) and they are commonly referred to as bloodlines. A Gambro Cartridge® Blood Set can be safely connected to hemodialyzers, vascular accesses and various perfusion lines, under the responsibility of the physician in charge.

Device Comparison Table

	PREDICATE Cobe Cartridge Blood Tubing Set	**MODIFIED DEVICE** Gambro Cartridge® Blood Set
Indication for Use	The Cobe Cartridge Blood Tubing Set may be used with the following hemodialysis devices: The Gambro Dasco Phoenix; The Gambro Model Cx, and the Cobe Centrysystem 3 (and 3+) Systems.	The Gambro Cartridge® Blood Set is intended for single use in a hemodialysis treatment using the Phoenix® and Centrysystem® 3 Dialysis Delivery Systems. The Low Weight model is used when a low extra-corporeal blood volume is recommended. The Low Weight model with a priming volume of 75 ml is indicated for patients with body weight greater than 20 Kg and lower or equal to 40 Kg. The standard models with a priming volume ranging from 103 ml to 162 ml are indicated for patients with body weight greater than 40 Kg.
Catalogue No.	Single Needle (SN): 003409-400 003409-410	Single Needle (SN): 003409-400 003409-410
	Double Needle (DN): 003410-500 003410-510 003411-500 003414-500	Double Needle (DN): 003410-500 003410-510 003411-500 003414-510 003414-500 003415-510 003410-710
	Single Needle conversion kit (SNK): 003429-500	Single Needle conversion kit (SNK): 003429-500
	Double Needle Pediatric (P): 003412-500	Double Needle Low Weight (LW): 003412-500

	PREDICATE Cobe Cartridge Blood Tubing Set	**MODIFIED DEVICE** Gambro Cartridge® Blood Set
Cartridge	Yes	Yes
Dialysis Machine Compatibility (U.S.)	Phoenix and Centrysystem 3	Phoenix and Centrysystem 3
Clamps	Pinch	Pinch
Blood Tubing Material	Soft PVC material	Soft PVC material with DEHP-free plasticizer
Blood Tubing Length	Patient length: SN: 198 cm DN: from 183 cm to 244 cm P: 183 cm	Patient length: SN: 198 cm DN: from 183 cm to 244 cm LW: 183 cm
	Dialyzer length (venous): SN: 46 cm DN: from 46 cm to 53 cm SNK: 46 cm P: 46 cm	Dialyzer length (venous): SN: 46 cm DN: from 46 cm to 53 cm SNK: 46 cm LW: 46 cm
	Dialyzer length (arterial): SN: 46 cm DN: from 30 cm to 46 cm SNK: 50 cm P: 30 cm	Dialyzer length (arterial): SN: 46 cm DN: from 30 cm to 51 cm SNK: 51 cm LW: 30 cm
Blood Tubing Thickness	Blood Pathway: SN-DN: 1.16 mm P: 1.62 cm	Blood Pathway: SN-DN: 1.16 mm SN-DN Connections to dialyzer lines: 1.32 mm LW: 1.63 mm
	Blood Pump segment: SN-DN: 1.59 mm P: 1.59 mm	Blood Pump segment: SN-DN: 1.59 mm LW: 1.59 mm
Priming Volumes	SN: 145 ml DN: from 103 ml to 120 ml SNK: 45 ml P: 75 ml	SN: 162 ml DN: from 103 ml to 119 ml SNK: 45 ml LW: 75 ml
Injection Plug Material	Latex-free	Latex-free
Packaging	Pouch	Blister
Sterilization Method	Radiation	Radiation
Expiration	3 years	3 years
Single Use	Yes	Yes
Storage Temperature	-18°C (0°F) and 49°C (120°F)	-18°C (0°F) and 49°C (120°F)

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Description and Conclusion of Testing	**Nonclinical Testing:** The non-clinical testing consisted of performance testing (bench) that included testing for biocompatibility, flow rate, validation of system injection ports (access sites), hemodialysis machine compatibility, mechanical hemolysis, expiration dating, integrity of the strength between connections, kink resistance, clamping of tubing and testing required by process to ensure compliance with other international standards applicable to extracorporeal blood circuit for hemodialysers.
	Conclusion: The successful non-clinical testing demonstrates the safety and effectiveness of the Gambro Cartridge® Blood Set when used for the defined indications for use and demonstrates that the device for which the 510(k) is submitted performs as well as or better than the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

OCT 12 2007

Mr. Thomas B. Dowell
Quality Systems Program Manager
Gambro® Renal Products
10810 W. Collins Avenue
LAKEWOOD CO 80215

Re: K070414
Trade/Device Name: Gambro Cartridge® Blood Set
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FJK
Dated: July 9, 2007
Received: July 10, 2007

Dear Mr. Dowell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Gambro Renal Products
10810 West Collins Avenue
Lakewood, CO 80215

Indications for Use

510(k) Number (if known): K070414

Device Name: Gambro Cartridge® Blood Set

Indications for Use:

The Gambro Cartridge® Blood Set is intended for single use in a hemodialysis treatment using the Phoenix® and Centrysystem® 3 Dialysis Delivery Systems. The Low Weight model is used when a low extra-corporeal blood volume is recommended. The Low Weight model with a priming volume of 75 ml is indicated for patients with body weight greater than 20 Kg and lower or equal to 40 Kg. The standard models with a priming volume ranging from 103 ml to 162 ml are indicated for patients with body weight greater than 40 Kg.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K070414